

**REMARKS**

Applicants respectfully request entrance of the above claim amendments. Upon entrance of these claim amendments, claims 65-88 are pending in the application. Basis for the amendments may be found in at least one example on page 3 of the application as filed which states, "The cartilage extract typically comprises of one or more compounds extractable from cartilage, and preferably comprises glycosaminoglycans," and on page 4 of the application as filed which states, "the cartilage extract may come from other natural sources but may be from a synthetic source, i.e. synthetically or semi-synthetically prepared." Further basis may be found in claim 25 of the application as filed. Applicants respectfully submit that no new matter is added by these claim amendments.

**Claim Rejections under 35 U.S.C. § 112**

The Office Action alleges that claim 13 is indefinite because of the phrase "one or more compounds extractable therefrom." This phrase has been deleted and replaced with the phrase "glycosaminoglycan-containing extract from cartilage." Applicants respectfully submit that this amendment obviates this rejection.

The Office action alleges that claim 13 to be indefinite because of the recitation of the term "derivative". The recitation of this term has been deleted from the claim. As such, Applicants respectfully submit that this amendment obviates this rejection.

In accordance with the Examiner's suggestion, the phrases "said composition increases collagen synthesis" and "Test Method A" have been deleted from the claims.

In accordance with the Examiner's suggestion, the language previously used in claim 19 regarding grape seeds has been amended accordingly in the new claim 71. Applicants respectfully submit that this amendment obviates this rejection.

Applicants have amended the language used in deleted claim 23 to which the Examiner objected and deleted reference to the tomato variety in new claim 74. Reference to the phrase

“MMP-1”, which was objected to in claim 30, has been deleted from the new claim set. Likewise, reference to the phrases “Test Method B” and “Test Method C”, which were objected to in claims 30 and 32, respectively, have been deleted from the claims. The claims have been amended to correct for inadequate antecedent basis in claims 35 and 36. As such, Applicants respectfully submit that these amendments obviate the rejections.

**Claim Rejections under 35 U.S.C. § 102**

Claims 13-20, 24 and 32 were rejected as allegedly being anticipated by Greenberg (US 5,569,458). However, Applicants respectfully submit that Greenberg does not define a composition comprising lycopene.

Greenberg defined a composition comprising a number of minerals, vitamins and extracts. In terms of anti-oxidants, Greenberg lists that the formulation further includes at least one anti-oxidant selected from the group of beta-carotene, vitamin B6, pantothenic acid, selenium, vitamin E, zinc, L-glutathine, DL-methionine, SOD glutathine peroxidase, coenzyme Q10, silymarin, and proanthocyanidin (column 5, line 55- column 6, line 2). This exhaustive list does not comprise lycopene.

Moreover, the list of ingredients for the formulation of a typical formulation according to Greenberg (column 2, lines 63-67 to column 3, lines 5-28), despite disclosing over 30 active ingredients, does not disclose lycopene or chondroitin sulfate as active ingredients. Furthermore, lines 29-46 of column 3, which further lists possible agents, does not disclose lycopene or herbs from which lycopene may be extracted. Greenberg does not disclose lycopene or herbs from which lycopene may be extracted as an ingredient in the formulations of the invention.

Furthermore, Greenberg does not specifically disclose that lipophilic and hydrophilic antioxidants must both be present in the formulation. }

The claims as amended in the present invention claim a composition comprising as an essential feature lycopene, such that at least one of the one or more lipophilic antioxidants is

lycopene. Thus, Applicants respectfully submit that claim 65--and claims 66 through 101 which are dependent therefrom--are not anticipated by Greenberg. For at least the foregoing reasons, Applicants respectfully request removal of these rejections in view of Greenberg.

**Claim Rejections under 35 U.S.C. § 103**

The Office Action states that the claims are allegedly obvious in view of Greenberg and Bombardelli et al. (EP 0,659,402) and/or Kosbab (WO 00/07607).

**Greenberg (US 5,569,458)**

As discussed, *supra*, Greenberg does not disclose a composition comprising lycopene and has not recognized the advantage of lycopene in the treatment of various skin conditions.

In actuality, the compositions of Greenberg are designed for a different purpose. Greenberg teaches that the composition provides "improved absorption of the nutrients into the body" and "increased blood circulation in the brain" (column 1, lines 7-9), and that the invention "is a dietary supplement formulation . . . for enhancing human nutrition" (column 4, lines 21-23).

Thus, the skilled artisan would not consider the teachings of Greenberg at all when attempting to develop a composition for improving skin conditions.

Moreover, Greenberg teaches that the formulation is "synergistically balanced" (column 3, line 30). Greenberg further states that the amounts of the nutrients are selectively adjusted "raising some (levels) and lowering others", "adjusting the nutrient levels recommended by the RDA" (column 5, line 46-47). Greenberg further teaches that "due to chemical reactions and competition between nutrients, the overall effectiveness of most supplements is drastically reduced when dozens of vitamins and minerals simultaneously arrive in the digestive system" (column 5, lines 10-13). Thus, Applicants respectfully submit that Greenberg teaches that a composition other than his own is not expected to be beneficial.

Greenberg discloses a solution to this problem by balancing the pH and stating that ingredients must be chosen in order "that (they) do not negatively interact" (column 5, line 15).

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Greenberg is therefore providing a solution for a particular problem which bears little resemblance to the present invention.

Furthermore, Greenberg does not specifically recognize or teach that the formulation should contain both lipophilic and hydrophilic anti-oxidants, with or without cartilage extract. The composition according to Greenberg must include (i) "at least one herb"; (ii) "at least one digestive enzyme"; and (iii) "at least one substance capable of balancing the chemical pH . . . (the substance being) goldenscal, dandelion or chamomile" (column 6, lines 37-52).

Again, the skilled artisan would not consider the teachings of Greenberg at all when attempting to develop a composition for improving skin conditions and, if coincidentally aware of the teachings in this different technical field, would not be able to derive a teaching used in the present invention.

**Bombardelli et al. (EP 0,659,402)**

Bombardelli does not teach the advantages of lycopene for treating skin conditions. *Functional intended use*  
Moreover, Bombardelli does not teach the advantage of combining lipophilic antioxidants such as lycopene and hydrophilic antioxidants for improving various skin conditions. The teachings of Bombardelli are in a technical field removed from the present invention and address altogether different health issues.

Moreover, Bombardelli does not disclose a composition comprising cartilage or a glycosaminoglycan-containing extract, or synthetic forms of glycosaminoglycans, nor the advantage of such compositions for treating skin conditions. Additionally, there is no teaching in Bombardelli of increased collagen synthesis or decreased formation of advanced glycosylation end products resulting from a composition comprising (lycopene) lipophilic and hydrophilic antioxidants.

Rather, Bombardelli discloses a combination of hydrophilic antioxidants with lycopene. Further, Bombardelli teaches the reader to combine silymarin with lycopene to reduce oedema

(Table 3). The compositions according to Bombardelli are intended for use in the field of oedema, antimutagenesis such as prevention of cancer and cardiovascular pathologies (page 3, statement 0015).

Given Bombardelli and Greenberg are directed to altogether different health concerns than the present invention and different health issues than the each other, the skilled person would not be motivated to combine them. In the event the skilled artisan would combine the teachings of Greenberg and Bombardelli, (s)he would not derive from these that combining a cartilage extract containing glycosaminoglycans with lycopene and with one or more hydrophilic antioxidants is expected to lead to a beneficial effect in any of technical field and particularly not in connection to skin conditions.

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Intended  
Use*

#### **Kosbab (WO 00/07607)**

According to Table 2 of Kosbab, lycopene does not have collagen maintenance or collagen synthesis function (see p.32, antioxidant carotenoids are not listed as having function 3 defined as for collagen maintenance and collagen synthesis.). Thus, Kosbab, by explicit absence of associating the function of lycopene to collagen synthesis or maintenance, teaches against an essential feature of the invention; namely the use of lycopene in compositions for skin health at least in part due to collagen maintenance.

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Intended  
Use*

Consequently Kosbab does not recognize or teach the advantage of compositions of the present invention for treating skin conditions.

Further, Kosbab discloses on page 12, line 5 that "maintenance and restoration of the collagen matrix in vascular and other tissue . . . is an important aspect of the formulations of this invention." Yet, despite the importance of "maintenance and restoration of the collagen matrix," Kosbab is silent to the use of lycopene for this purpose. Kosbab goes on (page 12, lines 5-21) to list several possible factors that may promote collagen synthesis, such as minerals, cofactors for synthesis, regulatory agents, growth regulators and glucosamine. Thus, several

alternative ways of promoting collagen maintenance and restoration of collagen matrix for the amelioration of cancer are disclosed.

Specifically, the teachings of Kosbab relate “to nutrient composition and to therapeutic compositions for the amelioration of cancer” (page 1, lines 4-5), and further that “the formulas of the present invention contain components which inhibit the development of cancer cells, inhibit proliferation of cancer cells and inhibit metastasis” (page 1, lines 17-19).

Formulations disclosed in Kosbab comprise a range of compounds, such as plant extracts, tea polyphenols, minerals such as zinc, chromium, calcium, magnesium, potassium, manganese, and selenium, soy isolate, amino acids, omega-3-fatty acids, and a range of additional components listed in the Formulae disclosed on pages 23-29 and in Table 2. These formulations are “useful in ameliorating cancer” (page 30, line 1), but can be combined in “formulas or drugs for the treatment of osteoporosis” (page 30, line 3).

The Office Action cites page 24, line 6, of Kosbab as disclosing a composition comprising cartilage or chondroitin sulphate and an antioxidant-containing plant extract. This citation relates to a cancer preventive/therapeutic composition defined as Formula I wherein the composition comprises (i) antioxidants from (a) possible combination of hydrophilic and hydrophobic antioxidants from plants or (b) a combination of vitamin C and vitamin E and (ii) a neovascular regulator wherein one of the named neovascular regulator may be cartilage or chondroitin sulphate. Again, lycopene is not suggested. There is nothing in that citation, in itself or in combination with the remainder of Kosbab or any of the other cited materials that the composition of the invention as claimed in amended form are of benefit for the treatment of skin conditions.

The general teaching of Kosbab thus relates to a wide range of formulations for a specific functional use, i.e. the amelioration of cancer and osteoporosis. Kosbab does in no way teach or suggest that the composition may be used in the treatment of skin conditions, and in fact clearly indicates that the formulations provided are for a distinct, different, functional use.

The antioxidant and collagen synthesis effects cited by the Office Action (page 43, lines 8-9 and page 44, lines 10-14) are thus claimed for very specific conditions, i.e. cancer and osteoporosis, and the person skilled in the art would not transfer those benefits to different disorders, such as skin disorders. Given the teaching as to the treatment for one disorder is not transferable to another unrelated disorder, there is no teaching in the cited documents of using the compositions of the present invention, nor for their use in treating skin conditions.

Thus, Greenberg does not teach the use of lycopene, Bombardelli does not teach lycopene for skin maintenance nor the use of a cartilage or suitable extract therefrom and Kosbab does not teach that lycopene has collagen maintenance or collagen synthesis function. Thus, the present invention relating to a combination of lycopene, glycosaminoglycans and one or more hydrophilic antioxidants is not obvious from the combined teachings of the cited documents.

**CONCLUSION**

For at least the foregoing reasons, Applicants respectfully request that the obviousness rejection be removed as the claims are distinguished over Greenberg, Bombardelli, and Kosbab-- either by themselves or in combination.

Applicant respectfully submits that the application is in condition for allowance and respectfully requests a notice of allowance for the pending claims. Should the Examiner determine that any further action is necessary to place this application in condition for allowance the Examiner is kindly requested and encouraged to telephone Applicant's undersigned representative at the number listed below.

It is believed that a three-month extension of time is due in connection with this response. The Assistant Commissioner is hereby authorized to charge fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required now or hereafter, or credit any overpayment, to Deposit Account No. 50-0206.

Respectfully submitted,

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By: \_\_\_\_\_

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